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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. AUROBINDO PHARMA LTD., AUROBINDO PHARMA U.S.A., INC., and AUROLIFE PHARMA LLC, Defendants.	:	Civil Action No._____ **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs" or "Takeda"), for their Complaint against Defendants Aurobindo Pharma Ltd., Aurobindo Pharma U.S.A., Inc., and Aurolife Pharma LLC (collectively, "Defendants" or "Aurobindo"), allege as follows:

THE PARTIES

1. Plaintiff Takeda Pharmaceutical Company Limited ("Takeda Japan") is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. As part of its business, Takeda Japan is involved in the research, development, and marketing of pharmaceutical products. Takeda Japan manufactures lansoprazole orally disintegrating tablets.

2. Plaintiff Takeda Japan is the owner of record and assignee of U.S. Patent No. 6,328,994 (" '994 Patent"), U.S. Patent No. 7,431,942 (" '942 Patent"), U.S. Patent No. 7,875,292 (" '292 Patent"), and U.S. Patent No. 7,399,485 (" '485 Patent") (collectively, "the patents-in-suit").

3. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A.") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda U.S.A. is involved in the research, development, and marketing of pharmaceutical products. Takeda U.S.A. is the registered holder of approved New Drug Application No. 21-428. In addition, Takeda U.S.A. has the exclusive right to import lansoprazole orally disintegrating tablets into the United States. Takeda U.S.A. purchases from Takeda Japan and imports into the United States, lansoprazole orally disintegrating tablets manufactured by Takeda Japan.

4. Plaintiff Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield,

Illinois 60015. As part of its business, Takeda America is involved in the purchase, sale, and marketing of pharmaceutical products. Takeda America has the exclusive right to purchase lansoprazole orally disintegrating tablets from Takeda U.S.A. and sell those tablets to the public in the United States. Takeda America sells lansoprazole orally disintegrating tablets manufactured by Takeda Japan that it purchases from Takeda U.S.A. to the public in the United States.

5. On information and belief, defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Telangana, India. On information and belief, Aurobindo Pharma Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this District.

6. On information and belief, defendant Aurobindo Pharma U.S.A., Inc. ("Aurobindo USA") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810, and is a wholly-owned subsidiary of Aurobindo Pharma Ltd. On information and belief, Aurobindo USA is in the business of, among other things, manufacturing, selling, and marketing generic copies of branded pharmaceutical products throughout the United States, including in this District.

7. On information and belief, defendant Aurolife Pharma LLC ("Aurolife") is a corporation existing under the laws of the State of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810, and is a wholly-owned subsidiary of Aurobindo USA. On information and belief, Aurolife is in the business of, among other things,

manufacturing and selling generic copies of branded pharmaceutical products throughout the United States, including in this District.

8. On information and belief, Aurobindo Pharma Ltd., Aurobindo USA, and Aurolife operate and act in concert as an integrated, unitary business for purposes of manufacturing, marketing, selling, and distributing generic pharmaceutical products.

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

9. This action arises under the patent laws of the United States of America, Title 35, United States Code.

10. On December 11, 2001, the United States Patent and Trademark Office ("PTO") issued the '994 Patent, entitled "Orally Disintegrable Tablets," to Takeda Chemical Industries, Ltd. (now Takeda Pharmaceutical Company Ltd.), the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '994 Patent. A copy of the '994 Patent is attached hereto as Exhibit A.

11. On October 7, 2008, the PTO issued the '942 Patent, entitled "Orally Disintegrable Tablets," to Takeda Pharmaceutical Company Limited, the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '942 Patent. A copy of the '942 Patent is attached hereto as Exhibit B.

12. On January 25, 2011, the PTO issued the '292 Patent, entitled "Orally Disintegrable Tablets," to Takeda Pharmaceutical Company Limited, the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '292 Patent. A copy of the '292 Patent is attached hereto as Exhibit C.

13. On July 15, 2008, the PTO issued the '485 Patent, entitled "Rapidly Disintegrable Solid Preparation," to Takeda Pharmaceutical Company Limited, the assignee of the named

inventors Toshihiro Shimizu, Masae Sugaya, and Yoshinori Nakano. Plaintiff Takeda Japan is the record owner of the '485 Patent. A copy of the '485 Patent is attached hereto as Exhibit D.

14. On August 30, 2002, the United States Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg. Plaintiff Takeda U.S.A. is the holder of NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, which Plaintiff Takeda America sells under the name Prevacid® SoluTab™.

15. The patents-in-suit are listed in a FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") for Prevacid® SoluTab™, lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg.

16. On information and belief, through the coordinated efforts of its staff worldwide, Defendants seek to constantly expand the range of generic products they sell.

17. On information and belief, Defendants collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to an approved abbreviated new drug application) within the United States generally and the State of New Jersey specifically.

18. On information and belief, Defendants actively review pharmaceutical patents and seek opportunities to challenge those patents.

19. On information and belief, Defendants reviewed the patents-in-suit and certain commercial and economic information relating to Prevacid® SoluTab™, including estimates of the revenues generated by the sale of Prevacid® SoluTab™, and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market lansoprazole delayed release orally disintegrating tablets.

20. On information and belief, Defendants collaborated in the research, development, preparation and filing of ANDA No. 207167 for lansoprazole delayed release orally disintegrating tablets.

21. On information and belief, Aurobindo Pharma Ltd. submitted to FDA ANDA No. 207167 seeking approval to engage in the commercial manufacture, use, and sale of lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg, prior to the expiration of the patents-in-suit.

22. Plaintiffs received a letter from Aurobindo Pharma Ltd., dated September 11, 2015, notifying Plaintiffs that ANDA No. 207167 includes a certification under 21 U.S.C. 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Aurobindo Pharma Ltd.'s opinion, no valid, enforceable claim of the patents-in-suit will be infringed by the commercial manufacture, use, or sale of the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 207167.

23. On information and belief, Aurobindo Pharma Ltd. collaborated with Aurobindo USA and Aurolife for the purpose of preparing and filing ANDA No. 207167 with FDA.

24. Defendants were aware of the patents-in-suit when Aurobindo Pharma Ltd. filed its ANDA No. 207167 with a Paragraph IV certification.

25. Plaintiffs commenced this action within 45 days of the date they received Aurobindo Pharma Ltd.'s notice of ANDA No. 207167 containing the Paragraph IV certification.

26. On information and belief, Aurobindo Pharma Ltd., Aurobindo USA, and Aurolife will continue to collaborate in seeking approval of ANDA No. 207167 from FDA and intend to collaborate in the commercial manufacture, marketing, and sale of lansoprazole delayed

release orally disintegrating tablets (including commercial marketing and sale of such products in the State of New Jersey) in the event that FDA approves ANDA No. 207167.

JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

28. On information and belief, this Court has jurisdiction over Aurobindo Pharma Ltd. because, *inter alia*, Aurobindo Pharma Ltd. collaborated with Aurobindo Pharma USA and Aurolife in the State of New Jersey for the purpose of preparing and submitting ANDA No. 207167 to FDA.

29. On information and belief, this Court also has jurisdiction over Aurobindo Pharma Ltd. because, *inter alia*, Aurobindo Pharma Ltd. has purposefully availed and avails itself of the legal protections of the State of New Jersey. Aurobindo Pharma Ltd. stated in a purported Offer of Confidential Access, dated September 11, 2015, that "[t]his Offer of Confidential Access shall be governed by the laws of the State of New Jersey." On information and belief, Aurobindo Pharma Ltd. has also established several related companies having their principal places of business in New Jersey. On information and belief, Aurobindo USA, a wholly-owned subsidiary and agent of Aurobindo Pharma Ltd., is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. On information and belief, Aurolife, an indirect subsidiary of Aurobindo Pharma Ltd. and a wholly-owned subsidiary of Aurobindo USA, is a corporation organized and existing under the laws of Delaware, having its principal place of business at 2400 US HWY 130 N., Dayton, New Jersey 08810. On information and belief, Auromedics Pharma LLC, an indirect subsidiary of Aurobindo Pharma Ltd. and a wholly-owned subsidiary of Aurobindo USA, is a corporation organized and existing under the laws of

Delaware, having its principal place of business is at 6 Wheeling Road, Dayton, New Jersey 08810.

30. On information and belief, this Court further has jurisdiction over Aurobindo Pharma Ltd. because, *inter alia*, Aurobindo Pharma Ltd., directly or through its wholly-owned subsidiaries Aurobindo USA and Aurolife, manufactures, imports, markets, distributes, and sells generic pharmaceutical products throughout the United States, including the State of New Jersey. On information and belief, Aurobindo Pharma Ltd. purposefully has conducted and continues to conduct business, directly or through its wholly-owned subsidiaries Aurobindo USA and Aurolife in the State of New Jersey, and this District is a likely destination of Aurobindo Pharma Ltd.'s generic pharmaceutical products. On information and belief, Aurobindo Pharma Ltd. derives substantial revenue in the State of New Jersey from sales of its generic pharmaceutical products, and has availed and avails itself to the privilege of conducting business within this District.

31. Aurobindo Pharma Ltd. has also previously consented to personal jurisdiction in this District. *See e.g., Shionogi & Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 15-cv-00319 (MAS)(LHG) (D.N.J.); *The Medicines Co. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 3:14-cv-02367 (PGS)(DEA) (D.N.J); *Otsuka Pharmaceutical Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 14-03306 (JBS)(KMW) (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 14-06890 (JBS)(KMW) (D.N.J.). Aurobindo Pharma Ltd. has further previously availed itself of this Court's jurisdiction by asserting counterclaims in other civil actions in this District. *Id.*

32. On information and belief, this Court has jurisdiction over Aurobindo USA because, *inter alia*, Aurobindo USA has its principal place of business in New Jersey and is

registered with the State of New Jersey as a drug wholesaler under Registration Number 5003120. Also, on information and belief, Aurobindo USA actively participated in the preparation and submission of Aurobindo Pharma Ltd.'s ANDA No. 207167 to FDA.

33. Aurobindo USA has also previously consented to personal jurisdiction in this District. *See e.g., Shionogi & Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 15-cv-00319 (MAS)(LHG) (D.N.J.); *The Medicines Co. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 3:14-cv-02367 (PGS)(DEA) (D.N.J); *Otsuka Pharmaceutical Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 14-03306 (JBS)(KMW) (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 14-06890 (JBS)(KMW) (D.N.J.). Aurobindo USA has further previously availed itself of this Court's jurisdiction by asserting counterclaims in other civil actions in this District. *Id.*

34. On information and belief, this Court has jurisdiction over Aurolife because, *inter alia*, Aurolife has its principal place of business in New Jersey and is registered with the State of New Jersey as a drug manufacturer and wholesaler under Registration Number 5003810. Also, on information and belief, Aurolife actively participated in the preparation and submission of Aurobindo Pharma Ltd.'s ANDA No. 207167 to FDA.

35. Aurolife has also previously consented to personal jurisdiction in this District. *See e.g., See e.g., Otsuka Pharmaceutical Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 14-03306 (JBS)(KMW) (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 14-06890 (JBS)(KMW) (D.N.J.). Aurolife has further previously availed itself of this Court's jurisdiction by asserting counterclaims in other civil actions in this District. *Id.*

36. On information and belief, this Court further has jurisdiction over Aurobindo USA and Aurolife because, *inter alia*, Aurobindo USA and Aurolife operate in concert with Aurobindo Pharma Ltd. to manufacture, import, market, distribute, and sell generic pharmaceutical products throughout the United States, including the State of New Jersey. On information and belief, Aurobindo USA and Aurolife, in concert with Aurobindo Pharma Ltd., purposefully have conducted and continue to conduct business in the State of New Jersey, and this District is a likely destination of Defendants' generic pharmaceutical products. On information and belief, Aurobindo USA and Aurolife derive substantial revenue in the State of New Jersey from sales of their generic pharmaceutical products, and have availed and avail themselves to the privilege of conducting business within this District.

37. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '994 Patent by Defendants)

38. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 37 hereof, as if fully set forth herein.

39. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '994 Patent.

40. By filing ANDA No. 207167 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets products described therein, prior to the expiration of the '994 Patent with pediatric exclusivity, Defendants have infringed the '994 Patent under 35 U.S.C. § 271(e)(2).

41. Defendants were aware of the existence of the '994 Patent prior to filing ANDA No. 207167 but took such action knowing that it would constitute infringement of the '994 Patent.

42. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '994 Patent.

43. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

44. Takeda will be irreparably harmed if Defendants are not enjoined from infringing the '994 Patent.

SECOND CLAIM FOR RELIEF
(Inducement of Infringement of the '994 Patent by Aurobindo USA and Aurolife)

45. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 44 hereof, as if fully set forth herein.

46. Through the conduct alleged above, Aurobindo USA and Aurolife have knowingly and actively induced Aurobindo Pharma Ltd. to infringe, and continue to infringe, one or more claims of the '994 patent.

47. By reason of Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '994 Patent, Aurobindo USA and Aurolife have caused and continue to cause irreparable harm to Plaintiffs.

48. On information and belief, Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '994 Patent will continue unless enjoined by this Court.

49. Plaintiffs have no adequate remedy at law for Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '994 Patent.

50. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

THIRD CLAIM FOR RELIEF
(Direct Infringement of the '942 Patent by Defendants)

51. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 50 hereof, as if fully set forth herein.

52. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '942 Patent.

53. By filing ANDA No. 207167 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets products described therein, prior to the expiration of the '942 Patent with pediatric exclusivity, Defendants have infringed the '942 Patent under 35 U.S.C. § 271(e)(2).

54. Defendants were aware of the existence of the '942 Patent prior to filing ANDA No. 207167 but took such action knowing that it would constitute infringement of the '942 Patent.

55. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '942 Patent.

56. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

57. Takeda will be irreparably harmed if Defendants are not enjoined from infringing the '942 Patent.

FOURTH CLAIM FOR RELIEF
(Inducement of Infringement of the '942 Patent by Aurobindo USA and Aurolife)

58. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 57 hereof, as if fully set forth herein.

59. Through the conduct alleged above, Aurobindo USA and Aurolife have knowingly and actively induced Aurobindo Pharma Ltd. to infringe, and continue to infringe, one or more claims of the '942 patent.

60. By reason of Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '942 Patent, Aurobindo USA and Aurolife have caused and continue to cause irreparable harm to Plaintiffs.

61. On information and belief, Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '942 Patent will continue unless enjoined by this Court.

62. Plaintiffs have no adequate remedy at law for Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '942 Patent.

63. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

FIFTH CLAIM FOR RELIEF
(Direct Infringement of the '292 Patent by Defendants)

64. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 63 hereof, as if fully set forth herein.

65. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '292 Patent.

66. By filing ANDA No. 207167 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release

orally disintegrating tablets products described therein, prior to the expiration of the '292 Patent with pediatric exclusivity, Defendants have infringed the '292 Patent under 35 U.S.C. § 271(e)(2).

67. Defendants were aware of the existence of the '292 Patent prior to filing ANDA No. 207167 but took such action knowing that it would constitute infringement of the '292 Patent.

68. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '292 Patent.

69. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

70. Takeda will be irreparably harmed if Defendants are not enjoined from infringing the '292 Patent.

SIXTH CLAIM FOR RELIEF
(Inducement of Infringement of the '292 Patent by Aurobindo USA and Aurolife)

71. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 70 hereof, as if fully set forth herein.

72. Through the conduct alleged above, Aurobindo USA and Aurolife have knowingly and actively induced Aurobindo Pharma Ltd. to infringe, and continue to infringe, one or more claims of the '292 patent.

73. By reason of Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '292 Patent, Aurobindo USA and Aurolife have caused and continue to cause irreparable harm to Plaintiffs.

74. On information and belief, Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '292 Patent will continue unless enjoined by this Court.

75. Plaintiffs have no adequate remedy at law for Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '292 Patent.

76. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

SEVENTH CLAIM FOR RELIEF
(Direct Infringement of the '485 Patent by Defendants)

77. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 76 hereof, as if fully set forth herein.

78. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '485 Patent.

79. By filing ANDA No. 207167 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets products described therein, prior to the expiration of the '485 Patent with pediatric exclusivity, Defendants have infringed the '485 Patent under 35 U.S.C. § 271(e)(2).

80. Defendants were aware of the existence of the '485 Patent prior to filing ANDA No. 207167 but took such action knowing that it would constitute infringement of the '485 Patent.

81. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '485 Patent.

82. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

83. Takeda will be irreparably harmed if Defendants are not enjoined from infringing the '485 Patent.

EIGHTH CLAIM FOR RELIEF
(Inducement of Infringement of the '485 Patent by Aurobindo USA and Aurolife)

84. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 83 hereof, as if fully set forth herein.

85. Through the conduct alleged above, Aurobindo USA and Aurolife have knowingly and actively induced Aurobindo Pharma Ltd. to infringe, and continue to infringe, one or more claims of the '485 patent.

86. By reason of Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '485 Patent, Aurobindo USA and Aurolife have caused and continue to cause irreparable harm to Plaintiffs.

87. On information and belief, Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '485 Patent will continue unless enjoined by this Court.

88. Plaintiffs have no adequate remedy at law for Aurobindo USA's and Aurolife's inducement of Aurobindo Pharma Ltd.'s direct infringement of the '485 Patent.

89. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Defendants have infringed the patents-in-suit;

B. An order adjudging and decreeing that Aurobindo USA and Aurolife have induced infringement of the patents-in-suit;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 207167 be no earlier than the expiration date of the last of the patents-in-suit, including any extensions and/or exclusivities;

D. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the lansoprazole products described in ANDA No. 207167 or any other ANDA not colorably different from ANDA No. 207167 until the expiration date of the last of the patents-in-suit, including any extensions and/or exclusivities;

E. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285 and costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: October 21, 2015

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that certain of the patents-in-suit in the above-captioned action are the subject of the following actions pending in this District: *Takeda Pharm. Co. Ltd. et al. v. Wockhardt Bio AG et al.*, Civil Action No. 3:13-06427 (MLC) (TJB) (D.N.J.); *Takeda Pharm. Co. Ltd. et al. v. Sun Pharma Global FZE et al.*, Civil Action No. 3:14-04616 (MLC) (TJB) (D.N.J.).

Respectfully submitted,

Dated: October 21, 2015

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